(19) Europäi che Pat ntamt
Europ an Patent Offi
Office européen d s brevets

(11) Publication number : **0 669 114 A1**

(12) EUROPEAN PATENT APPLICATION

(21) Application number : **95301035.2**

(51) Int. Cl.[6] : **A61F 2/06**

(22) Date of filing : **17.02.95**

(30) Priority : **25.02.94 US 202128**

(43) Date of publication of application :
30.08.95 Bulletin 95/35

(84) Designated Contracting States :
AT BE CH DE DK ES FR GB GR IE IT LI LU MC NL PT SE

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(54) Stent having a multiplicity of closed circular structures.

(57) An expandable stent that can be used in an artery or any other vessel of the human body forms a multiplicity of generally circular rings when expanded and provides a closed structure which optimizes hoop strength so as to minimize elastic recoil of the vessel into which the stent is inserted. The structure of the stent is initially in the form of folded ellipses or ovals which can be formed to a small diameter for percutaneous insertion by means of a stent delivery catheter. The ovals are joined to each other by either a straight or undulating shaped wires which are called "longitudinals" which serve to space the deployed rings within the vessel. Straight longitudinals are used in straight vessels and undulating longitudinals can be employed in either straight or highly curved vessels such as some coronary arteries.

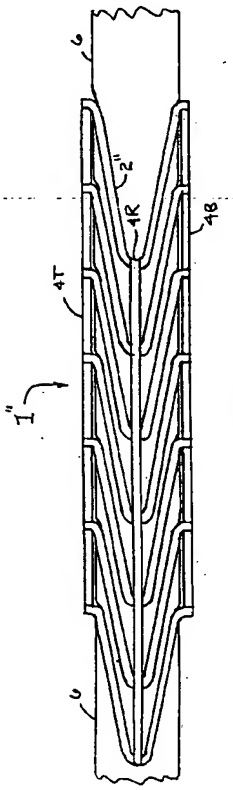

FIG. 6

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This invention is in the field of stents for maintaining patency of any one of a multiplicity of vessels of the human body.

In the last decade, many different designs of stents have been used to maintain patency of arteries and other vessels of the human body. In all such devices, hoop strength is an important characteristic. Specifically, the stent must have enough hoop strength to resist the elastic recoil exerted by the vessel into which the stent is placed. The Mass stent described in the U.S. Patent No. 4,553,545 and the Dotter stent described in U.S. Patent No. 4,503, 569 are each open helical coils. The Palmaz stent described in the U.S. Patent No. 4,733,665 is of the "chinese finger" design. The Gianturco-Rubin stent currently sold by Cook, Inc. is another stent design which like the stents of Mass, Dotter and Palmaz does not have any closed circular member to optimize hoop strength.

The ideal arterial stent utilizes a minimum wire size of the stent elements to minimize thrombosis at the stent site after implantation. The ideal arterial stent also posses sufficient hoop strength to resist elastic recoil of the artery. Although the optimum design for maximizing hoop strength is a closed circular structure, no prior art stent has been described which has a small diameter when percutaneously inserted into a vessel and which expands into the form of multiplicity of closed circular structures (i.e. rings) when expanded outward against the vessel wall.

In accordance with an aspect of the invention, there is provided a post-deployment stent structure for maintaining patency of a vessel of a human body comprising:

a multiplicity of closed, generally circular rings, the plane of each ring being generally parallel to the plane of each adjacent ring, the rings having a common longitudinal axis which is perpendicular to the plane of each ring and which longitudinal axis passes through the geometric centre of each ring; and

a multiplicity of elongated wire structures forming longitudinals which longitudinals are fixedly attached to the rings so as to be generally parallel to the longitudinal axis of the rings.

In accordance with another aspect of the invention there is provided an initial structure that is capable of being formed into a pre-deployment stent structure which in turn is capable of being deployed into a stent structure for placement within a vessel of the human body, the initial structure comprising:

a multiplicity of flat ovals, the plane of each oval being generally parallel to the plane of all other ovals, the ovals having a common longitudinal axis which is perpendicular to the plane of each oval and which longitudinal axis passes through the geometric centre of the ovals; and

a multiplicity of longitudinals which are fixedly attached to the ovals, the longitudinals being positioned onto the ovals so as to be generally parallel to the longitudinal axis of the ovals.

In accordance with a further aspect of the invention there is provided a generally cylindrical pre-deployment stent structure which is capable of being deployed into a post-deployment stent structure for placement within a vessel of the human body, the pre-deployment structure being formed from an initial structure which consists of a multiplicity of flat ovals, the plane of each oval being generally parallel to the plane of all other ovals, the ovals also having a minor axis and a major axis and a minor axis dimension and a major axis dimension; the ovals having a common longitudinal axis which is perpendicular to the plane of each oval and which longitudinal axis passes through the geometric centre of the ovals; and a multiplicity of longitudinals which are fixedly attached to the ovals, the longitudinals being positioned onto the ovals so as to be generally parallel to the longitudinal axis of the ovals;

the pre-deployment stent structure being formed by folding the ovals around a distal portion of a stent delivery catheter, the pre-deployment stent structure being adapted to form a post-deployment stent structure having a multiplicity of generally circular rings that are formed from the ovals, the circular rings being joined together by the longitudinals.

An embodiment of the invention provides an expandable stent that can be used in an artery or any other vessel of the human body which, when expanded, forms a multiplicity of generally circular rings whose closed structure optimizes hoop strength so as to minimize elastic recoil of the vessel into which the stent is inserted. Furthermore, the structure of an embodiment of the stent according to the present invention is initially in the form of folded ellipses or ovals which can be formed to a small diameter for percutaneous insertion by means of a stent delivery catheter. The ovals are joined to each other by either a straight or undulating shaped wires which are called "longitudinals" which serve to space the deployed rings within the vessel. Straight longitudinals are used in straight vessels and undulating longitudinals can be employed in either straight or highly curved vessels such as some coronary arteries.

An embodiment of the invention provides a stent having a maximum hoop strength by the employment of closed, generally circular structures which are in fact rings.

In an embodiment of the invention rings are initially in the form of ovals that can be folded to fit onto a cylindrical structure at a distal portion of a stent delivery catheter.

In an embodiment of the invention the fully deployed rings are spaced apart by means of longitudinals which are either straight of undulating wires that are placed to be generally parallel to the longitudinal axis of the vessel into which the stent is deployed.

In an embodiment of the invention the pre-de-

ployment stent structur is form d as a single pi ce out of metal tub having a small r inside diameter as compared to the outsid diamet r of an xpandable balloon onto which th pre-d ployment st nt is mounted.

An embodiment of the invention is described hereinafter, by way of example only with reference to the accompanying drawings, in which:

FIG. 1 is a side view of the stent after it has been deployed; i.e., in its post-deployment form;

FIG. 2 is a transverse cross section at section 2-2 of FIG. 1 illustrating how the longitudinals are joined to the rings;

FIG. 3 is a cross section at section 3-3 of FIG. 2 showing the joining of a single ring to the longitudinals;

FIG. 4 is a side view of the stent prior to being mounted onto a stent delivery catheter; i.e., in the form of an initial structure;

FIG. 5 is a transverse cross section at section 5-5 of FIG. 4 illustrating how the longitudinals are joined to the ovals;

FIG. 6 is a side view of a pre-deployment form of the stent structure in which the ovals have been folded into a small diameter cylinder that is placed around a deflated balloon situated near the distal end of a stent delivery catheter;

FIG. 7 is a partial side view of a pre-deployment stent structure showing only two of a multiplicity of folded ovals formed around an expandable balloon in which the ovals are folded in an alternative manner as compared with FIG. 6;

FIG. 8 is a side view of a post-deployment stent structure which utilizes two undulating longitudinals on opposite sides of the stent for improved placement in curved vessels; and

FIG. 9 is a side view of a stent as etched out of a small diameter metal cylinder as a single piece of metal.

FIG. 1 is a side view of an embodiment of a cylindrical stent 1 according to the present invention shown in its post-deployment configuration. The stent 1 has a multiplicity of rings 2 which are spaced apart by four wires called longitudinals. As seen in FIGS. 1 and 2, at the top of the stent is longitudinal 4T, at the bottom is longitudinal 4B, at the left side is longitudinal 4L and at the right side is longitudinal 4R. Although FIGS. 1 and 2 show 7 rings and 4 longitudinals, it is apparent that the stent can be made longer by adding rings or increasing the separation between rings. In a similar manner, the stent can be made shorter by reducing the number of rings or decreasing the spacing between rings. Also variable spacing of the rings is nvisioned for accomplishing a variety of purposes including increased hoop str ngth at a particular s ction of th st nt. Also, it is nvisioned that th two or more longitudinals could be utilized for this stent design with a maximum number being 32.

FIGS. 2 and 3 illustrate the joining of th longitudinals t th rings. Sp cifically th l ngitudinals can be placed into cutouts in th form of n tches 5 locat d on th outsid p rim t r f th ring 2. Th longitudinals can then be spot welded, adhesively bonded or joined by any variety of means to the rings 2. It is also envisioned that the longitudinals could be placed on the inside perimeter of the ring 2, or holes could be mechanically or laser drilled through the ring 2 for placement therethrough of the longitudinals.

FIGS. 4 and 5 illustrate a stent 1' shown in one particular form in which it could be fabricated; i.e., in an initial structure form. Specifically, FIGS. 4 and 5 show that this initial form of the stent 1' is a multiplicity of parallel ellipses or ovals 2' each oval having the same minor axis dimension m and major axis dimension M. The oval's minor axis passes through the center of the longitudinals 4L and 4R. The oval's major axis passes through the center of the longitudinals 4T and 4B. It is important to note that, if it is desired to have a final outside diameter D (as seen in FIG. 2) of the ring 2 after it is fully deployed, then it can be shown that D is given by the equation $D^2 = 1/2\ (m^2 + M^2)$.

To place the stent design of FIGS. 4 and 5 onto a balloon that is mounted near the distal end of a stent delivery catheter, it is necessary to fold the ovals 2' around that balloon. Specifically, the pre-deployment cylindrical stent 1" can be formed onto an expandable balloon 6 as shown in FIG. 6 by folding the ovals 2' about the dotted line F (which is the minor axis of the oval 2') as shown in FIG. 5. Specifically, as seen in FIG. 4, the top and bottom of the ovals 2' could be held stationery while the side longitudinals 4R and 4L are pushed to the left which results in the pre-deployment structure which is shown as the stent 1" in FIG. 6. An optimum design has the folded ovals 2" as shown in FIG. 6 with the stent 1" being a cylinder whose outside diameter is equal in size to the minor axis dimension m. When the balloon 6 of FIG. 6 is expanded, the pre-deployment stent 1" structure forms the post-deployment stent 1 structure having circular rings 2 as shown in FIGS. 1 and 2.

The stent 1"' is an alternative embodiment for a pre-deployment structure of the stent of the present invention as it is placed onto a balloon. Specifically, FIG. 7 shows 2 folded rings 2"' of a multiple ring stent 1"'. The stent 1"' being formed by holding the top and bottom of the stent 1' of FIG. 4 stationery while pushing the longitudinal 4R to the left and pushing the longitudinal 4L to the right. Like the stent 1" of FIG. 6, when mounted onto a balloon, the stent 1"' has a cylindrical shape with a diameter equal to the dimension m.

FIGS. 1 to 7 inclusiv illustrat stents that employ longitudinals that are form d from gen rally straight wires. FIG. 8 shows an alt rnativ mbodiment of a stent 10 that has two undulating longitudinals. Spe-

cifically, th l ft sid l ngitudinal 14L (shown as dotted lin s) and th right sid longitudinal 14R ar ach undulating shaped longitudinals. A stent such as stent 10 could have tw or mor undulating longitudinals. Such a stent would bend more easily during insertion into a vessel and would be more readily adaptable for placement in curved vessels such as some coronary arteries.

Typically, the rings and longitudinals of the stents would be made of the same material. Typical metals used for such a stent would be stainless steel, tantulum, titanium, or a shape memory metal such as Nitinol. If Nitinol is used, the stent would be heat treated into the shape at body temperature having circular rings 2 as shown in FIGS. 1 and 2. The rings could then be distorted into ovals as shown in FIGS. 4 and 5 and then mounted onto a stent delivery catheter which does not employ a balloon but is of the more general shape described in the previously cited U.S. Patent No. 4,553,545 by C.T. Dotter. Such a design would provide the desired stent structure having a multiplicity of generally circular rings instead of the Dotter design of a helical spring which inherently has a lesser hoop strength as compared to the present invention.

It should be understood that once the ovals are folded onto a stent delivery catheter, when they fully deploy, they do not form perfectly circular rings as shown in FIG. 2, but rather they are of a generally circular shape. Such comparatively small deviations from an exactly circular shape do not appreciably decrease hoop strength because they are in fact closed structures that are almost exactly circular.

It should also be understood that at least part of the end rings of the stent could be fabricated from or coated with a radiopaque metal such as tantalum or gold to provide a fluoroscopic indication of the stent position within a vessel. However, the other rings and the longitudinals could be made from a much less dense metal which would provide less obscuration of the central region within the stent. For example, the stent rings and longitudinals could all be fabricated from titanium or a titanium alloy except the end rings which could be formed from gold which is then plated with titanium. Thus, the entire outside surface of the stent would be titanium, which is known to be a comparatively non-thrombogenic metal while the gold in the end rings provides an improved fluoroscopic image of the stent extremities.

The dimensions of stent rings are typically 0.1 to 0.3 mm thick, with a width of 0.1 to 0.5 mm and an outside diameter D between 2.0 and 30.0 mm depending on the luminal diameter of the .vessel into which it is ins rt d. Th l ngth of th stent could be b tw en 1 and 10 cm. Th wir diameter for the longitudinals would typically b b tween 0.05 and 0.5 mm.

Although th designs of FIGS. 1 through 7 inclusiv illustrate separate longitudinals attached to a multiplicity of rings, this invention also cont mplates an initial st nt structur which is ch mically tch d from thin-walled tubing having an oval transvers cross section. Thus the val and longitudinals would be formed from a single piece of metal thus precluding the need for attaching the longitudinals to the rings. In a similar manner laser or EDM machining could be used to form the stent from a thin-walled tube.

It is further anticipated that a pre-deployment stent structure 20 as shown in FIG. 9 could be formed from a thin-walled cylindrical tube whose inside diameter is slightly smaller than the outside diameter of the balloon 6 shown in FIG. 6. A pattern such as that shown in either FIG. 6 or FIG. 7 could be photoetched onto a thin-walled metal cylinder. The one piece structure 20 shown in FIG. 9 has folded ovals 22 and longitudinals 23T, 24B, 24R and (not shown) 24L. This pre-deployment stent structure 20 could then be mounted onto the expandable balloon; the stent having sufficient elastic recoil to firmly grasp down onto the balloon.

Various other modifications, adaptations, and alternative designs are of course possible in light of the above teachings and within the scope of the invention.

Claims

1. A post-deployment stent structure for maintaining patency of a vessel of a human body comprising:
   a multiplicity of closed, generally circular rings, the plane of each ring being generally parallel to the plane of each adjacent ring, the rings having a common longitudinal axis which is perpendicular to the plane of each ring and which longitudinal axis passes through the geometric centre of each ring; and
   a multiplicity of elongated wire structures forming longitudinals which longitudinals are fixedly attached to the rings so as to be generally parallel to the longitudinal axis of the rings.

2. A stent according to claim 1, wherein the rings have a multiplicity of cutouts for the placement therethrough of the longitudinals.

3. A stent according to claim 2, wherein the cutouts on the rings are notches.

4. A stent according to claim 3, wherein the notches on th rings are located at the outside perimet r of each ring.

5. A st nt according to claim 3, wh r in th notches are located at the inside perimeter of each ring.

6. A stent according to claim 2, wherein the cut outs are holes drilled through the rings.

7. A stent according to any one of the preceding claims, wherein the longitudinals are essentially straight wires.

8. A stent according to any one of the preceding claims, wherein at least two of the longitudinals are of an undulating shape.

9. A stent according to any one of the preceding claims, wherein the longitudinals are welded to the rings.

10. A stent according to any one of the preceding claims, wherein the rings and longitudinals are made from or coated with titanium.

11. A stent according to any one of the preceding claims, wherein the end rings are more radiopaque as compared to any other ring.

12. A stent according to any one of the preceding claims, wherein the stent is formed from a metal having a shape memory characteristic.

13. An initial structure that is capable of being formed into a pre-deployment stent structure which in turn is capable of being deployed into a stent structure for placement within a vessel of the human body, the initial structure comprising:
a multiplicity of flat ovals, the plane of each oval being generally parallel to the plane of all other ovals, the ovals having a common longitudinal axis which is perpendicular to the plane of each oval and which longitudinal axis passes through the geometric centre of the ovals; and
a multiplicity of longitudinals which are fixedly attached to the ovals, the longitudinals being positioned onto the ovals so as to be generally parallel to the longitudinal axis of the ovals.

14. An initial structure according to claim 13 wherein the ovals and the longitudinals are formed form a single piece of metal.

15. A generally cylindrical pre-deployment stent structure which is capable of being deployed into a post-deployment stent structure for placement within a vessel of the human body, the pre-deployment structure being formed from an initial structure which consists of a multiplicity of flat ovals, the plane of each oval being generally parallel to the plane of all other ovals, the ovals also having a minor axis and a major axis and a minor axis dimension and a major axis dimension; the ovals having a common longitudinal axis which is perpendicular to the plane of each oval and which longitudinal axis passes through the geometric centre of the ovals; and a multiplicity of longitudinals which are fixedly attached to the ovals, the longitudinals being positioned onto the ovals so as to be generally parallel to the longitudinal axis of the ovals;
the pre-deployment stent structure being formed by folding the ovals around a distal portion of a stent delivery catheter, the pre-deployment stent structure being adapted to form a post-deployment stent structure having a multiplicity of generally circular rings that are formed from the ovals, the circular rings being joined together by the longitudinals.

16. A pre-deployment stent structure according to claim 15 wherein the ovals are folded around an expandable balloon located near the distal end of the stent delivery catheter.

17. A pre-deployment stent structure according to claim 15 wherein the ovals are folded around the oval's minor axis to form a generally cylindrical shape that can be mounted onto a stent delivery catheter.

18. A pre-deployment stent structure according to claim 15 wherein one side of the ovals is folded in one direction and the opposite side of the ovals is folded in the opposite direction to form a pre-deployment structure of generally cylindrical shape.

19. A pre-deployment stent structure according to any one of claims 15 to 18 wherein the outer diameter of the generally cylindrical pre-deployment stent structure is approximately the same as the minor axis dimension of the oval.

20. A pre-deployment stent structure according to claim 15 wherein the stent structure is a cylinder formed from a single piece of metal, the cylinder being slightly smaller in its inside diameter as compared to the outside diameter of an expandable balloon located at a distal portion of a stent delivery catheter onto which the stent structure is mounted.

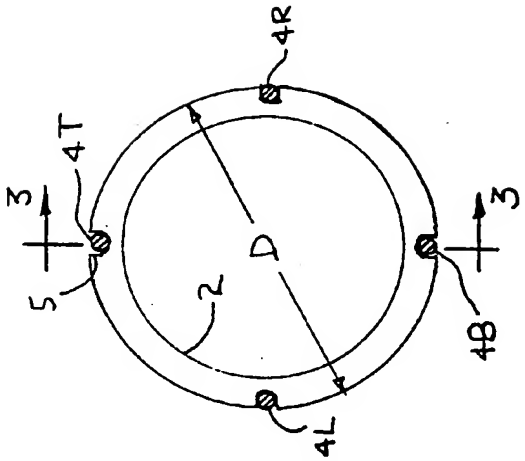

FIG. 2

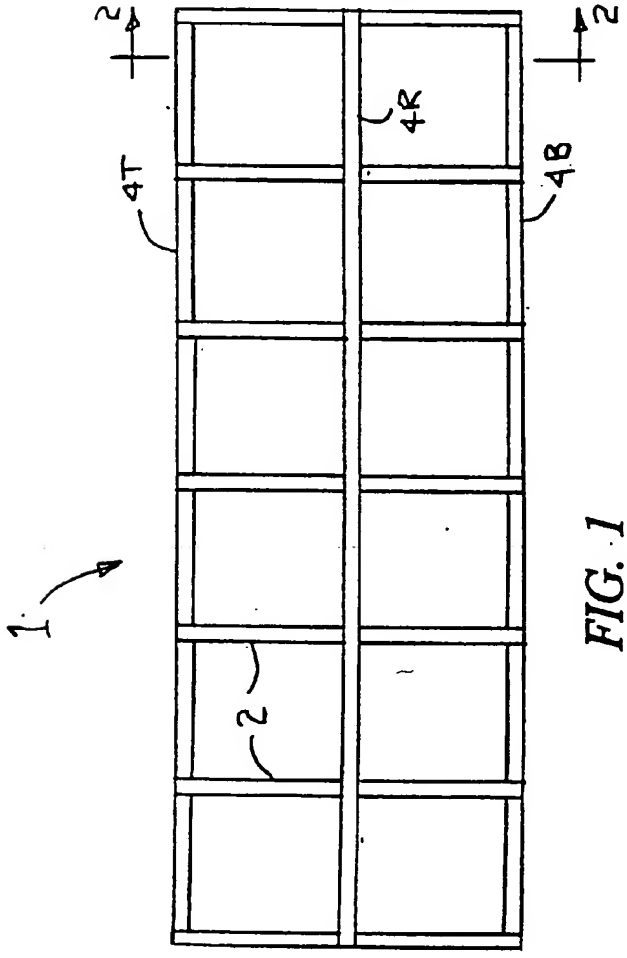

FIG. 1

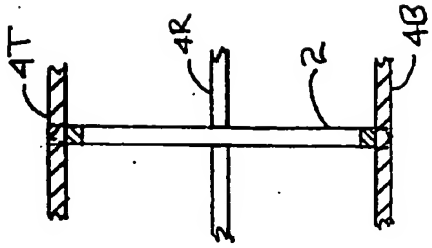

FIG. 3

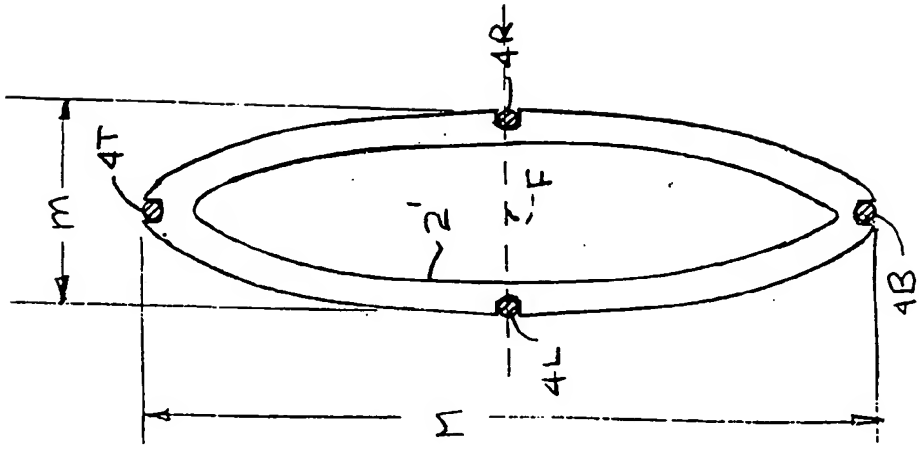

FIG. 5

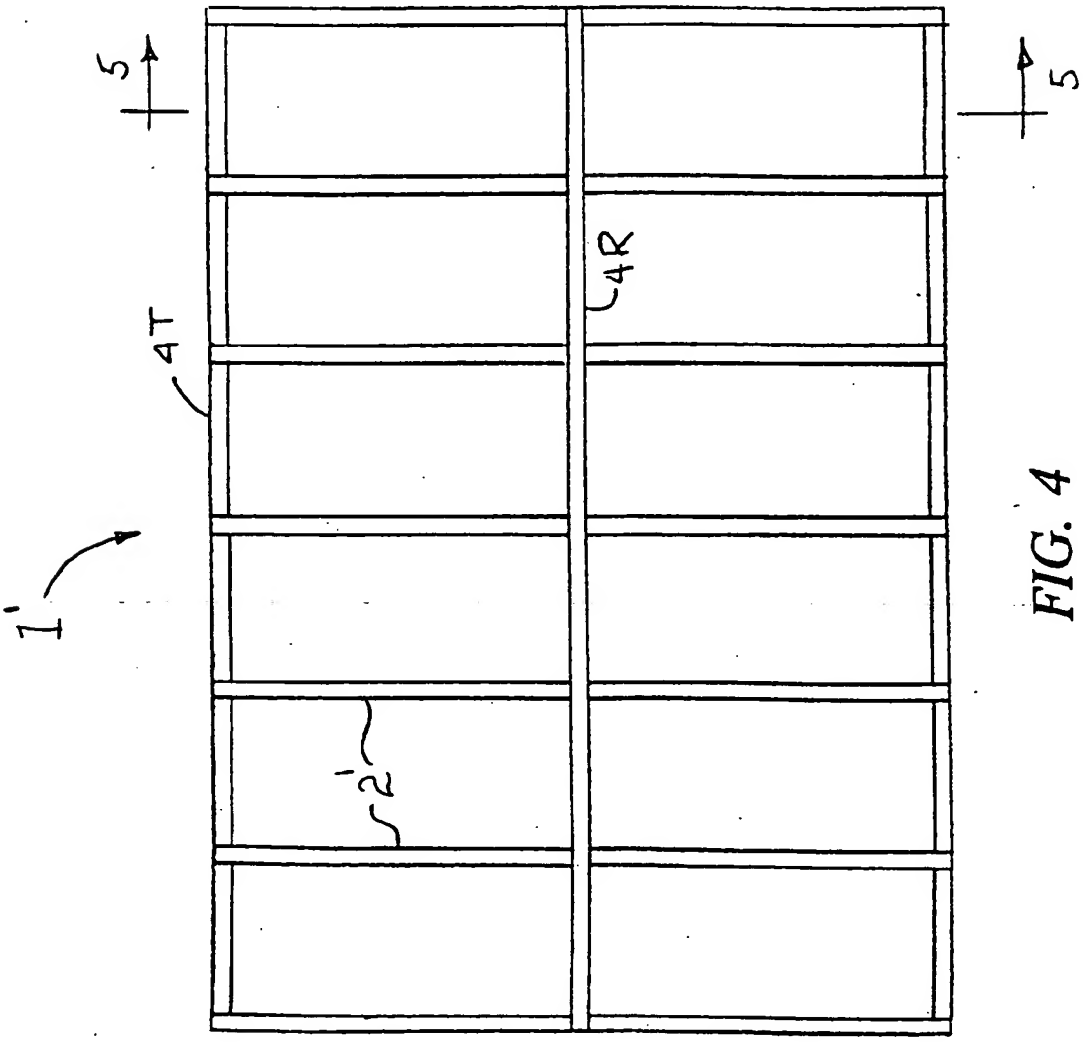

FIG. 4

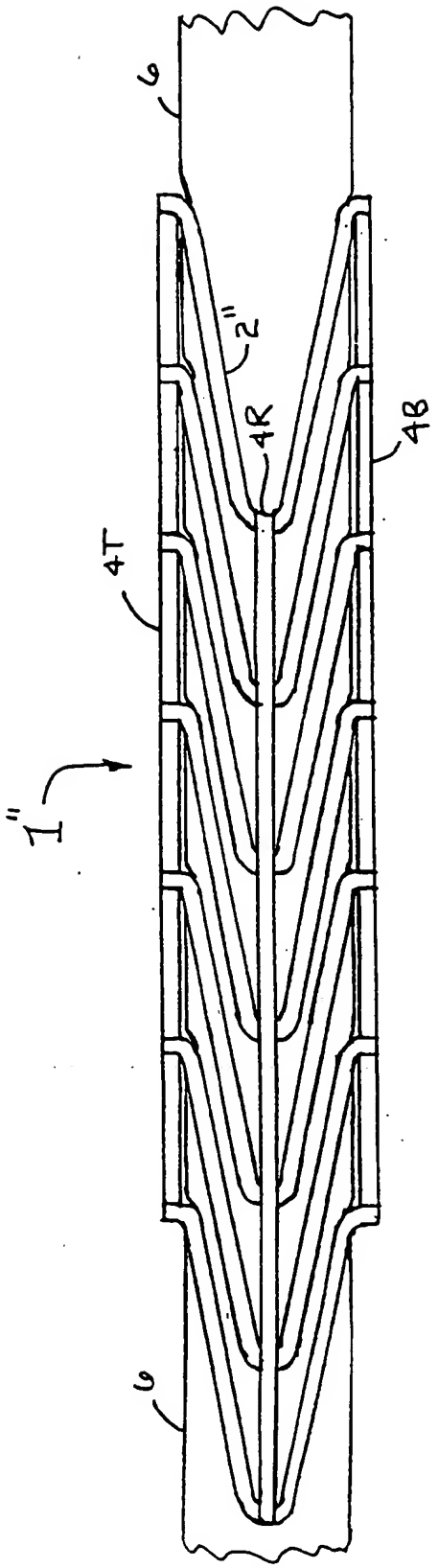

FIG. 6

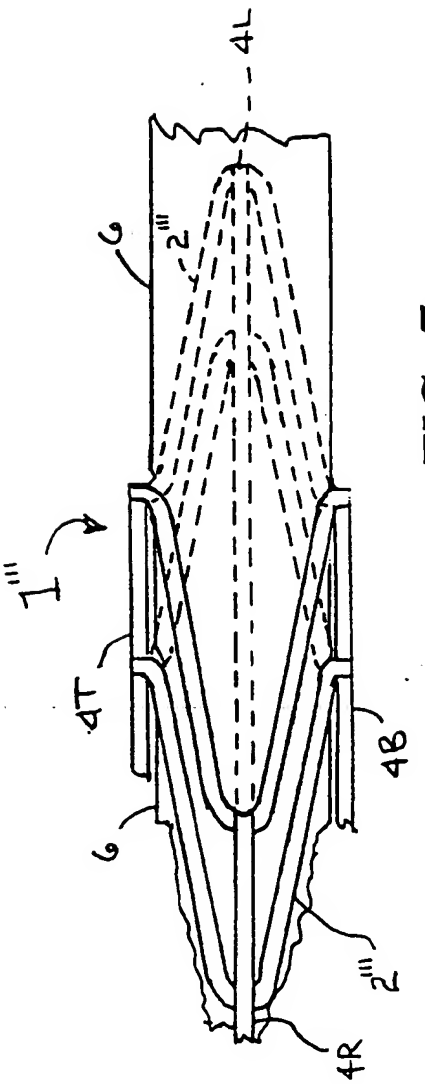

FIG. 7

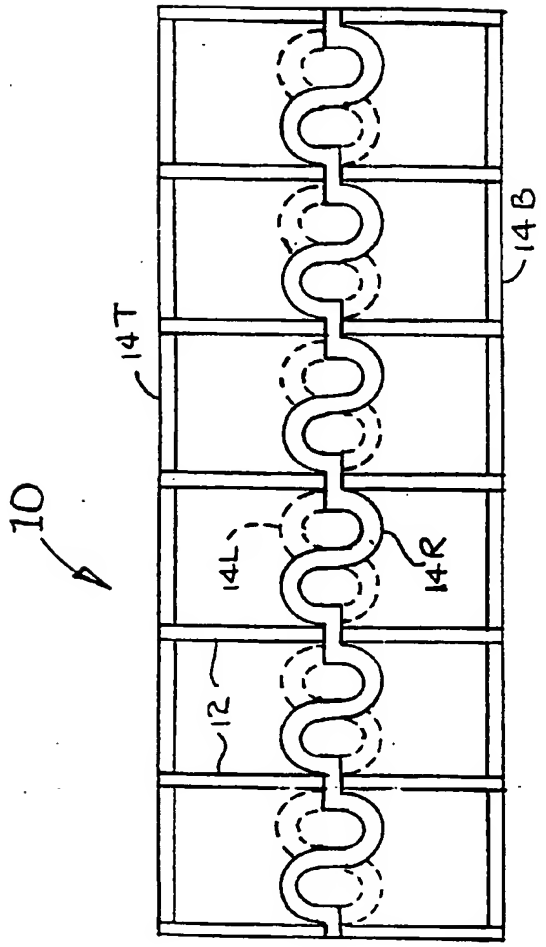

FIG. 8

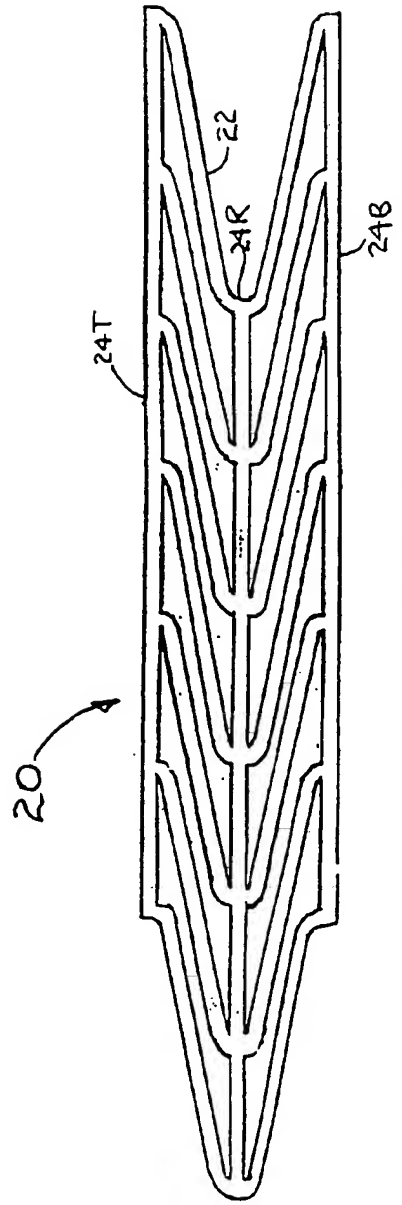

FIG. 9

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 95 30 1035

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
X Y A	EP-A-0 566 807 (SGRO) * abstract; figures * ---	1 2-5,7-9, 12 13-20	A61F2/06
Y	GB-A-2 189 150 (MEDINVENT) * page 5, line 11-25; figures * ---	2-5,12	
Y	EP-A-0 472 731 (INOUE) * figures * ---	7	
Y	US-A-4 856 516 (CORDIS) * claim 1; figures * ---	8	
Y	GB-A-1 205 743 (DIDCOTT) * page 1, line 96 - page 2, line 12; figures * ---	9	
A	EP-A-0 579 523 (COTTENCEAU) * figure 16 * -----	1	

TECHNICAL FIELDS SEARCHED (Int.Cl.6)

A61F

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	2 June 1995	Steenbakker, J

CATEGORY OF CITED DOCUMENTS

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